PREDICTORS OF PATIENTS' MENTAL ADJUSTMENT TO CANCER AMONG BREAST CANCER WOMEN IN YEMEN

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ABSTRACT

Introduction The breast cancer is an extremely stressful experience and having a serious impact on many aspects of women' life. Which make women prone to psychological and emotional disturbances. Some studies have appeared an important role for the personal factors in determining the level of mental adjustment of women with the diagnosed of breast cancer. Therefore, the study aims to identify the potential predictors that influence the mental adjustment in women who are diagnosed with breast cancer.

Methods: A cross-sectional survey as a part of PhD experimental thesis out among 112 participants. The participants were selected using two random sampling technique (SRS) for 56 participants and group matching for the others (56) participants. The selected from the three national oncology centers in Sana'a, Hadhramaut and Aden. The personal characteristics were collected through a pretest questionnaire and mental adjustment was measured by using Mini-MAC scale -29. The multiple regression analysis was used to detect the significant predictors.

Results: The analysis had been conducted on 112 participants. The results showed that the personal characteristics were significant predictors of the mental adjustment; the personal characteristics explained 85% of changes in the cognitive avoidance scores (F (7, 94) = 34.77, p < 0.001, R2 = 0.85), explained 78% of changes in the anxious preoccupation scores (F (8, 93) = 18.26, p < 0.001, R2 = 0.78), explained 73% of changes in the helplessness / hopelessness scores (F (8, 93) = 31.87, p < 0.001, R2 = 0.73), while the relationships was very week (14%) with the fighting spirit (F (3, 98) = 5.19, p < 0.05, R2 = .14) and was no significant with the fatalism domain.

Conclusion: The study indicated that there was strength of relationship between the clinical and sociodemographic factors and mental adjustment in breast cancer women. The age was the greater predictor for the mental adjustment to cancer, as well as, the level of education, income,

marital status, and type of surgery were significant predictors for the mental adjustment among women with breast cancer in Yemen.

Keywords: mental adjustment; coping; predictor; sociodemographic factors; clinical characteristics

1.0 Introduction

The breast cancer is reported to be one of the significant public health problems worldwide. It is the most commonly diagnosed cancer, contributing 11.6 % of the total number of new cases diagnosis (1, 2). In Yemen, the breast cancer is the most common type of cancer among women, accounting for 32.3% of all diagnosed cancers (3, 4), it appears more at younger ages compared to the other countries (5-8).

The cancer attacks the most valuable thing in women's life; where, the breast constitutes a part of their aesthetic appearance, identity and symbol of motherhood, their femininity and affects their loved ones (9-12). Furthermore, the changes in her body structure, such as, hair loss, removal of one or both breasts, are terribly stressful issues for women suffering from this illness. This may be equivalent to the loss of their femininity and feeling of disfigured appearance, resulting in developing an inferiority complex (13). In addition to the cancer diagnosis itself, the cancer treatment side effects lead to myriad of physical and mental disturbances (14, 15).

Consequently, once a woman knows she has breast cancer, she feels terrified, scared, worried, experience immense sadness (16, 17), the hopelessness and fear of dying (18). Therefore, the breast cancer is responsible for physical and mental disorders (19), it makes women prone to psychological disturbances, low quality of life and hopelessness toward the future (20-22). It leaves dramatic and adverse effects on their life (23). Being diagnosed with breast cancer is likened to facing death in the face (24).

Several studies indicated that the level of patients' acceptance to the cancer is related to sociodemographic and clinical characteristics (25, 26). Syrowatka et al., (2017) reviewed forty-two eligible studies. They established a set of the sociodemographic and clinical characteristics can be used to determine the level of distress of women with breast cancer. In another study, Mazanec et al., (2011) reported that the sociodemographic characteristics predict 52% of the variability in adjustment to cancer (26).

In Yemen, according to the available studies, the patients sociodemographic factors differences than other patients in the other countries. The larger groups of breast cancer patients in Yemen are under 50 years of age (represented 69.6%), and they are the high risk group to the psychological distress (5-8). These results are inconsistent with the average age in the regional countries, above 50 years, (27-30), above than 55 years in developed countries (31), (32), (33), (34) and (35). Moreover, the literacy rate among cancer patients are more than 60% of the patients (36), (37). Several Yemeni studies and reports indicated that the Yemeni breast cancer

present to the cancer treatment in late-cancer stages (7), (37) (38), (37, 38), while, the majority of breast cancer patients in other countries present in stage I (39), (40), (34), (41), (42) and (43). Unfortunately, in Yemen, there is no study had been conducted to determine the predictors of the adjustment to cancer (helplessness/hopelessness, anxious preoccupation, fighting spirit and cognitive avoidance) in the breast cancer patients. Therefore, this study aims to investigate the potential predictors that influence mental adjustment in women who are diagnosed with breast cancer in Yemen. Therefore, the results can be help to identify the potential predictors that influence the mental adjustment in women who are diagnosed with breast cancer.

2.0 Methods

2.1 Study Design and Location

The study was a part of a PhD thesis had been conducted in UPM university, Malaysia. In this thesis, the researcher used quasi-experimental repeated measure with a control group design to achieve proper answering for the research questions. Determining of the predictors of the mental adjustment was a second main objective, and it was achieved at the baseline survey as cross-sectional survey. The study was conducted in the three main oncology centers in Yemen, which received the patients from all governorates; National Oncology Centre in Sana'a (NOCS), National Oncology Centre in Hadhramaut (NOCH) and National Oncology Centre in Aden (NOCA). Selecting of the participants from three locations had granted more representation of the population in Yemen, and avoid the threat to the external validity of the study.

2.2 Sample Size and Sampling Technique

The sample size was calculated using the formula for a two-sample problem to test the hypothesis for two population means, developed by the Lemeshow, Hosmer (44), at significance level of 0.05 (1.96) and power 80% (0.84), $n = (2\sigma^2 [Z_{-}(1 - \alpha) + Z_{-}(1 - \beta)]^2)/[\mu_{-}1 - \mu_{-}2]^2$. The mean $\mu_1 = 20.4$, $\mu_2 = 19$ and standard deviation (S); $S_1^2 = (20.4)^2$ and $S_2^2 = (19.0)^2$ were extracted from the study of Banerjee, Vadiraj (45), to determine the standard deviation, the following formula was applied: $S_p^2 = [S_1^2 + S_2^2]/2 = (20.4)^2 + (19.0)^2/2 = 12.25/2 = 6.125$. n = 2 (6.125) [1.960+0.84]2/(20.4-19)2 = 49 participants. Adding 7 (14.37%) for the attrition rate, hence, this gave of 56 participants for each arm (control and intervention); with an overall 112 participations.

The study population comprised of women who were diagnosed with non-metastatic breast cancer as a first time; the diagnosis has been confirmed by histopathological test, and they were registered in chemotherapy sessions lists. The participants in the intervention group were chosen randomly using the systematic random sampling technique (SRS) based on the inclusion criteria. While the participants in the control group were chosen by using the group matching. The inclusion criteria included; 1- age: over 18 years, 2- non pregnant, 3- diagnosed: breast cancer for the first time; 4- type of stage I, II or III.

2.3 Data collection tool

Three trained nurses interviewed the participants and filled the questionnaires. Semi-structured questionnaires were used to obtain information on participants' sociodemographic and clinical characteristics. The adjustment to cancer was measured by using the Mini-Mental Adjustment to Cancer (Mini-MAC). The Mini-MAC scale consisted of 29 items on a four-point Likert Scale and was grouped into the same five dimensions; helplessness/hopelessness, anxious preoccupation, fighting spirit, avoidance and fatalism (46).

2.4 Data analysis

The data were analysed using the Statistical Package for Social Sciences (SPSS) statistics, version 23. The statistically significant results were tested by calculating the p-value at the significance level of 0.05 ($P \le 0.05$). The questionnaires were filled by the researcher assistant team to avoid the missing data and treated missing at the same time. The data were screened and reviewed (data entry, case screening, and variables screening). After that, the data were organised, summarised, and presented in a convenient and informative way (via frequency distribution and tables). The quantitative variables described by using Mean and SD, while the categorical variables described by using the percentage.

The multiple regression analysis (stepwise methods) was used to detect the significant predictors of the adjustment in breast cancer patients. The categorical variables were converted to dummy variables. To assess whether the model fits the data well, Cook's distance, the Leverage values and Outliers were evaluated. The regression model assumptions were assessed includes Multicollinearity, Tolerance, Durbin-Watson, and scatter plot to evaluate normality, linearity and homoscedasticity.

3.0 Results

3.1 Characteristics of participants

Demographic characteristics of the sample are summarized in Table 1. Overall, 112 breast cancer patients, non-metastases cancer, participated in the study, and their mean age was 43.4 years, SD: 11.1 years. They were mostly in low of education 88% (illiterate and school level), while 12% had a graduate degree. The majority of participants 86.3% had not jobs, and 14.7% had not regular income, 59.8% get less than 40,000 YER ((1 U\$D = 560.17 YER / I MR = 138 YER), while 25.5% of them get 40,000 to 120,000 YER monthly, for more information refer to the Table 1.

| Characteristics | Frequency | Mean (± SD) | Percentage % |
|--------------------------------------|-----------|-------------|--------------|
| Age ¹ | 112 | 43.4 (11.1) | - |
| BMI ⁵ | 112 | 24.9 (4.8) | - |
| Underweight | 11 | - | 9.8 |
| Healthy weight | 44 | - | 39.2 |
| Overweight | 38 | - | 34.3 |
| Obesity | 19 | - | 16.7 |
| Educational level | - | | - |
| Illiterate | 54 | - | 48.0 |
| School ² | 45 | - | 40.2 |
| Graduate | 13 | - | 11.8 |
| Residence address | - | | - |
| Rural | 49 | _ | 44.1 |
| Urban | 63 | - | 55.9 |
| Marital status | - | | - |
| Single | 10 | - | 8.8 |
| Married | 86 | - | 76.5 |
| Widowed/Divorced | 16 | - | 14.7 |
| Type of Job | - | | - |
| Private | 5 | - | 4.9 |
| Public | 10 | - | 8.8 |
| Has not job | 97 | - | 86.3 |
| Monthly household income | - | | - |
| Nothing | 16 | | 14.7 |
| Less than 40.000 YER ³ | 67 | - | 59.8 |
| 40,000 – 120,000 YER ³ | 29 | - | 25.5 |
| Physical activities | - | | - |
| Practice physical exercise | 4 | - | 2.9 |
| Practice a moving during the work at | - | | |
| home ⁴ | 93 | - | 83.3 |
| Nothing | 15 | - | 13.7 |

Table 1: Sociodemographic Characteristics of the Study Population (n=112)

¹ The age was estimated by year

² School: included primary and secondary education according to the education hierarchy in Yemen

³ YER: Yemeni Riyal, it is the local currency and officially (1 UD = 560.17 YER / I MR = 138 YER

⁴ Practice of movement during patient' daily work in her home

⁵ BMI: body max index

3.2 The Participants' Clinical Characteristics

Clinical medical characteristics of the sample are summarized in Table 2. The most of participants presented in late stage 71 (62.8%) stage II and 36 (32.4%) stage III, while only 5 (4.9%) who presented in early stage (stage I). Accordingly, 87 (77.5%) of them had undergone mastectomy surgeries, and 14 (12.8%) had undergone lumpectomy surgery, while 11 (9.8%) of participants did not have any surgical intervention, for more information refer to the Table 2.

| Characteristics | Frequency | Percentage % | |
|-----------------------------|-----------|--------------|--|
| Cancer Stage | - | - | |
| Stage I | 5 | 4.9 | |
| Stage II | 71 | 62.8 | |
| Stage III | 36 | 32.4 | |
| Type of surgery | - | | |
| Lumpectomy | 14 | 12.8 | |
| Mastectomy | 87 | 77.5 | |
| No surgery ¹ | 11 | 9.8 | |
| Comorbidities ² | - | | |
| Yes | 21 | 18.6 | |
| No comorbidities | 91 | 81.4 | |
| Menstrual status | - | | |
| Premenopausal | 65 | 57.8 | |
| Postmenopausal | 33 | 29.4 | |
| Menopausal due to treatment | 14 | 12.8 | |
| Family history of cancer | - | | |
| Yes | 29 | 25.5 | |
| No | 83 | 74.5 | |

Table 2: Clinical Characteristics of the Study Population (n=112)

¹ The patient received cancer treatment without surgical intervention

² Presence of one or more additional non-communicable chronic diseases with current cancer

3.3 The Mental Adjustment Scores

The mental adjustment was measured by using the Mini-Mac scale. As can be seen from the Table 3, the helplessness/hopelessness was 66.4 %, and anxious preoccupation 69.4 %. As well as, fighting spirit was 51.5 %, and the cognitive avoidance was 53.1 %, while the fatalism was 78.2 %.

Table 3: Mini-Mac Results at Baseline Survey (n=112)

| Characteristics | Frequency | Mean (SD) | |
|---------------------------|-----------|--------------|--|
| Mini-MAC scale 29 items | | | |
| Mini-Mac/ HH** | 112 | 66.4* (11.7) | |
| Mini-Mac/ AP** | 112 | 69.4* (11.2) | |
| Mini-Mac/ FS** | 112 | 51.5* (14.1) | |
| Mini-Mac/ CA** | 112 | 53.1*(13.5) | |
| Mini-Mac/ F ^{**} | 112 | 78.2* (9.2) | |

* The scales outcomes have been converted into percentage

** HH: helplessness-hopelessness; AP: anxious preoccupation; FS: fighting spirit; CA: cognitive avoidance; F: fatalism

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3.4 The significant predictors of the Mental Adjustment to Cancer

3.4.1 The Predictors of the Helplessness / Hopelessness

The stepwise regression was calculated to predict the helplessness / hopelessness (HH) based on the all covariates sociodemographic and clinical characteristics.

The results yielded significant regression equation (F (8, 93) = 31.87, p < 0.001, R² = .73): age β = -0.87, t (100) = -9.94, p < 0.001, mastectomy β = 0.37, t (100) = 5.24, p < 0.001, comorbidities β = 0.26, t (100) = 4.71, p < 0.001, monthly income β = -.178, t (100) = -3.02, p < 0.05, no surgery β = -.23, t (100) = -3.31, p < 0.05, widower β = -.217, t (100) = -3.31, p < 0.05, employment status β = -.17, t (100) = -2.88, p < 0.05, and stop menstruation β = 0.12, t (100) = 2.84, p < 0.05. Therefore, as can be concluded that the participants' predicted helplessness / hopelessness is: \hat{Y} = 96.10 - 0.91 (age) + 10.28 (mastectomy) + 7.80 (co-morbidities) - 4.83 (monthly income) - 9.06 (no surgery) - 6358 (widower) - 5.59 (employment status) + 5.69 stop menstruation.

3.4.2 The Predictors of the Anxious Preoccupation

The stepwise regression was calculated to predict the anxious preoccupation based on the potential factors included age, marital status, education status, residence, employment, monthly income, financial sponsor, BMI, chewing khat, smoking shisha family history, stage of cancer, type of surgery, menstruation status, and co-morbidities. A significant regression equation was found (F (8, 93) = 18.26, p < 0.001, R2 = .78): the level education β = -0.24, t (100) = -3, p < 0.05, age β = -0.56, t (100) = -8.02, p < 0.001, the family history β = -0.39, t (100) = 5.80, p < 156 0.001, mastectomy β = 0.42, t (100) = 6.10, p < 0.001, widower β = 0.31, t (100) = 4.48, p < 0.001, co-morbidities β = 0.21, t (100) = 3.05, p < 0.05, has a job β = -0.16, t (100) = -2.02, p < 0.05 and stage III β = -0.13, t (100) = -1.997, p < 0.05. Therefore, as can be concluded that the participants' predicted the anxious preoccupation is: \hat{Y} = 88.36 – 8.53 (graduate level) – 0.57 (age) – 9.990 (family history) + 11.13 (mastectomy) + 9.75 (widower) + 5.90 (co-morbidities) - 5.26 (has a job) – 3.19 (stage III).

3.4.3 The Predictors of the Fighting Spirit

The stepwise regression was calculated to predict the fighting spirit based on the potential factors included marital status, education status, residence, employment, financial sponsor, physical activity, chewing khat, smoking shisha family history, stage of cancer. A significant regression equation was found (F (3, 98) = 5.19, p < 0.05, R2 = .14): the single status β = 0.21, t (100) = 2.215, p < 0.05, the graduate level β = 0.21, t (100) = 2.21, p < 0.05, and second stage of cancer β = 0.19, t (100) = 2, p < 0.05. Therefore, as can be concluded that the participants' predicted the fighting spirit is: \hat{Y} = 46.08 + 10.38 (single status) + 9.08 (graduate level) + 5.48 (second stage of cancer).

3.4.5 The Predictors of the Cognitive Avoidance

The stepwise regression was calculated to predict the cognitive avoidance based on the potential factors included age, marital status, education status, residence, employment, monthly income, financial sponsor, BMI, physical activity, chewing khat, smoking shisha family history, type of surgery, menstruation status and comorbidities. A significant regression equation was found (F (7, 94) = 34.77, p < 0.001, R2 = 0.85): illiterate $\beta = -0.30, t (100) = -4.68, p < 0.001$, employment status $\beta = -0.27, t (100) = -3.99, p < 0.001$, comorbidities $\beta = -0.28, t (100) = -5.01, p < 0.001$, age $\beta = -0.29, t (100) = -4.85, p < 0.001$, practice exercise $\beta = 0.20, t (100) = 3.61, p < 0.001$, mastectomy $\beta = -0.16, t (100) = -2.75, p < 0.05$, and graduate variable $\beta = 0.16, t (100) = 2.29, p < 0.05$. Therefore, as can be concluded that the participants' predicted the cognitive avoidance is: $\hat{Y} = 85.83 - 3.54$ (age) - 8.10 (illiterate) - 10.48 (employment status) - 9.75 comorbidities + 15.92 practice exercise - 5 mastectomy + 6.63 graduate.

3.4.6 The Predictors of the Fatalism

All dependent variables were entered in the correlation model, the results appeared that there was no statistically significant association between the independent variables and fatalism, refer to the Table 4.20. Stepwise regression, Backward and Enter method were used, the results appeared that there was no relationship between the independent variables and fatalism.

| Study variable | Domain | Diagnosis ¹ | Assumptions ² | R- squared ³ | F (d.f.) | P value ⁴ | Predictors |
|-----------------------------------|-------------------------------|------------------------|--------------------------|------------------------------|-------------------|-------------------------|--|
| Mental adjustment to cancer | Helplessness/ hopelessness | Model fit | Assumptions met | 0.73 | 31.87 (8,93) | Sig. | Age, mastectomy, co-morbidities, monthly income, type of surgery, marital status, has a job and stop menstruation |
| | Anxious Preoccupation | Model fit | Assumptions met | 0.78 | 18.26 (8,93) | Sig. | Education level, age, family history, type of surgery, marital status, comorbidities, employment status and type of stage. |
| | Fighting Spirit | Model fit | Assumptions met | 0.14 | 5.19 (3,98) | Sig. | Marital status, education level and cancer stage |
| | Cognitive Avoidance | Model fit | Assumptions met | 0.85 | 34.77 (7,94) | Sig. | Age, education level, employment status, comorbidities, physical activity, and type of surgery |
| | Fatalism | Model fit | Assumptions met | No statistically significant | | | |

Table 3: The Predictors to the Adjustment to Breast Cancer in the Study Sample

¹ Diagnosis: evaluating of the outliers, Leverage and influential points.

² Assumptions met evaluating of the normality, Linearity, Homoscedasticity, Multicollinearity, Tolerance and Independent Errors.

³ R-squared is a coefficient of determination.

⁴ P value at the significance level of 0.05

4.0 Discussion

The study revealed that there were ten variables significantly predict the mental adjustment in breast cancer women in Yemen, based on the Mini-Mac scale. These predictors include, age, marital status, educational level, employment status, monthly income, type of surgery, comorbidities, family history, cancer stage, and physical activity. These findings are relatively consistent with a systematic review conducted by Moreover, Brandão, Schulz (47). They determined six sociodemographic variables as predictors; age, marital status, educational level, income, living alone. They found that these factors are predictors of psychological adjustment in breast cancer patients. Okano, Okamura (48), suggested that the age is a predictor of mental adjustment. Mishra and Saranath (49), reported that the socio-demography and medical characteristics were significantly predictor for the mental adjustment to cancer.

The results indicated that the age was a major significant indicator that determining the ability of women to cope with the breast cancer psychological implications. The mental adjustment in younger women was lower than older women at the diagnosed time. These findings agree with studies were conducted by Mazanec, Daly, Douglas, and Musil (2011) and Okano et al. (2001). They reported that the age was a major predictor of mental adjustment in breast cancer patients at the diagnosis time. However, the young women appeared better coping with cancer than older women over time Okano et al. (2001).

Helplessness / hopelessness (HH), the significant predictors include age, marital status, level of education, income, type of surgery and comorbidities. The relationship between the significant predictors and HH was inverse relationship; where the HH decrease as increase of age, monthly income, no surgery, widower, and has a job. Akechi, Okamura (50), reported that increasing of age, has a job and living alone are predictors for decrease the HH in breast cancer patients. Grassi, Travado (51), found an association between age and HH (51); Okano, Okamura (48), reported that the age is a predictor of HH. Inoue, Saeki (52) reported that the low income correlated with high HH. As well as a study in Korea, found that the predictors of HH in cancer patients were the education and advance of cancer predict the of HH score (53). Mishra and Saranath (49), reported that the age, income and social support were significant predictors of HH, and they explained 41% of the variance of the fighting spirit score in breast cancer patients. Brothers and Andersen (56), and (52), they reported that the patients who are living alone increase the hopelessness in breast cancer patients (52, 56).

Anxious Preoccupation (AP): The stepwise regression analysis yielded seven significant predictors for the anxious preoccupation in breast cancer patients were; level of education, family history, age, type of surgery, marital status, comorbidities and cancer stage. These predictors explained 78% of the variance in adjustment to cancer. Fighting Spirit (FS): the stepwise regression analysis yielded three significant predictors for the FS in breast cancer patients were; marital status, level of education, cancer stage. These predictors explained 14% variance in FS is explained by the single status, undergraduate level and second stage of cancer variables. In a study which has been conducted in Korea, the results indicated that faith, confidence in support and satisfaction of social support were the main predictors of the FS scores

(53). However, Inoue, Saeki (52), reported that high level of education is correlated with low FS score. As well as, Okano, Okamura (48) suggested that the age is a predictor of FS score. Mishra and Saranath (49), reported that the age, marital status, education and social support were significant predictors of FS, and they explained 43% of the variance of the FS score in breast cancer patients.

Cognitive Avoidance (CA): the stepwise regression analysis yielded seven significant predictors for the cognitive avoidance in breast cancer patients were; the level of education, employment status, comorbidities, age, exercise. These predictors explained 85% of variance in cognitive avoidance scores in breast cancer women in Yemen. Fatalism: the results appeared that there was no statistically significant relationship between the sociodemographic and clinical factors and fatalism. Stepwise regression, Backward and Enter method were used, the results appeared that there was no relationship between them. Similar results has been reported by Kissal, Ersin (57) in Turkey, they reported that there was no statistical significant association between the sociodemographic and perceptions of fear and fatalism. In surrounded countries, there are limited of studies have been investigated the relationship between the sociodemographic characteristics and fatalism.

There are some limitations in this study. Although the sample size was calculated through using an approved equation, the sample size still relatively small. But as a result of type of design, limited time and budget, the size of sample was accepted in this study. The study was conducted with patients who are diagnosed with cancer at first time and their cancer is non metastatic breast cancer. Therefore, the findings from this research can only be generalized to individuals with the characteristics of the patients in the sample. Moreover, the collection data team faced some challenges with the illiterate patients.

In conclusion, the study revealed that that there were strong relationships between some sociodemographic and clinical factors and the mental adjustment to breast cancer in women at time of breast cancer diagnosis. Moreover, the study had indicated that these factors explained large variation in the cognitive avoidance, the anxious preoccupation, and the helplessness/ hopelessness domains, but, they explained small variation in fighting spirit domain, while there was no relationship with the fatalism domain. The age was the greater predictor for the mental adjustment to cancer, where the younger women reported more psychological disturbance than older women at time of cancer diagnosis. As well as, the level of education, income, marital status, and type of surgery were significant predictors for the mental adjustment among women with breast cancer in Yemen.

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Author contributions

AA, MHJ and HB design the study, developed the study methodology and they followed the data collection. AA, AM and HBKS analysed the data and interpreted the results and drafted the manuscript. All authors finalized and approved the final version of the manuscript.

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Conflict of Interest:

The authors declare no conflict of interest exists.

Ethical approval

The Ethics and Research Committee of UPM university, JKEUPM Ref No. FPSK (EXP16) P161 date 7 July 2017. As well as, the Ministry of Public Health and Population in Yemen, Ref No. G7/85. As well as, a written informed consent was obtained from the participants.

Data sharing statement

The data in this study are confidential and cannot be publicly shared according the participants' informed consent. However, it is available from the corresponding author on reasonable request.

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